5.0 TRADITIONAL 510(K) SUMMARY

JUN - 3 2010

Submitted by:
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Date of Summary: May 7, 2010

Device Trade Name: UltiMed UltiCare™ Disposable Pen Needles

Common or Usual Name: Pen Needles

Classification Name: Hypodermic single lumen needles (§880.5570)

Product Code: FMI

Predicate Device(s):
K002938: Becton Dickinson B-D Ultra-Fine™ III Pen Needle; Model 31 gauge x 3/16"
K031200: Becton Dickinson B-D Ultra-Fine™ Original Pen Needles (29 gauge x 1/2")
K063466: Daejin Tech Medical Manufacturing Co:, Ltd Top Fine® Insulin Pen Needles (29 – 32 gauge; 1/4" – 1/2")

Device Description: The UltiCare Disposable Pen Needles are sterile, single-use, Type A, hypodermic single lumen needles designed for use with insulin pen injector devices. The UltiCare Disposable Pen Needles consist of a double-ended cannula, a needle hub, a needle shield and the needle primary container. The UltiCare Disposable Pen Needles are non-toxic and non-pyrogenic, and are available in a variety of needle sizes (29 gauge to 32 gauge) and lengths (3/16" to 1/2").

Intended Use: The UltiCare Disposable Pen needles are used with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

Technological Characteristics:

The UltiCare Disposable Pen Needles are substantially equivalent in device description, function, principle of operation, and basic composition to the predicate devices.

The subject device and the predicate devices consist of a double-ended cannula, a needle hub, a needle shield and a needle primary container. The hollow steel cannula is ground at both ends. The upper (proximal) part of the cannula is surrounded by a plastic screw thread, the needle hub, so that the upper cannula end is totally hidden inside. After opening the sterile, primary container packaging, the proximal thread is screwed onto the pen injector thereby penetrating the seal of the cartridge inside the injector. The needle primary container is then removed. After activating the pen-injector and removing the needle shield from the lower (distal) part of the cannula, the patient end, the devices are ready for use for subcutaneous injection.

The UltiCare Disposable Pen Needles will be available in a range of needle gauges and lengths encompassed by the predicate devices.

Testing:

The UltiCare Disposable Pen Needles have been designed and tested to meet the requirements of voluntary standards and FDA guidance documents applicable to the subject and predicate devices. Results of the non-clinical testing supports the conclusion of substantial equivalence of the UltiCare Disposable Pen Needles to the predicate devices.

Performance Testing:

The UltiCare Disposable Pen Needles have been designed and successfully tested to meet the applicable requirements outlined in ISO 7864, ISO 9626 and ISO 11608-2.

Additional performance testing to internal standards include: paper sealing force, primary container capping force, and sharpness testing.

Biocompatibility Testing:

The materials of the UltiCare Disposable Pen Needles have successfully passed testing as outlined in ISO 10993-1 for devices categorized as External Communicating Devices, Circulating Blood, Limited Exposure.

Sterilization and Shelf-life Testing:

Sterilization of the UltiCare Disposable Pen Needles has been validated using the half-cycle method as outlined in ISO 11135. The maximum levels of residues of ethylene oxide and ethylene chlorohydrin will not exceed the limits presented in ISO 10993-7.

Shelf-life testing supports a shelf-life of 5-years after sterilization.

Clinical Data:

No prospective clinical trials were conducted in support of this Traditional 510(k).

Substantial Equivalence: The UltiCare Disposable Pen Needles are substantially equivalent to the intended use, function, principle of operation, and basic composition of the predicate devices. The non-clinical testing to voluntary standards and applicable FDA guidances provide evidence the UltiCare Disposable Pen Needles are substantially equivalent to the predicate devices in terms of safety, efficacy, and performance.

The minor differences between the UltiCare Disposable Pen Needles and the predicate devices, including needle gauge, needle length, and primary container material, raise no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN – 3 2010

UltiMed, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K100812
Trade/Device Name: UltiMed UltiCare™ Disposable Pen Needles
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 21, 2010
Received: May 24, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: To be determined.

Device Name: UltiMed UltiCare™ Disposable Pen Needles

Intended Use: The UltiCare Disposable Pen Needles are used with insulin pen injector devices for the subcutaneous injection of insulin in the treatment of diabetes.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use: **NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

)ivision Sign-Off)
)ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

510(k) Number: K100812